

Policy & Procedure (P&P)

Policy Title :

Donor Adverse Reactions and Donor Privacy

| Department | Index No. | Scope |
|-------------------------|----------------------|----------------------|
| Laboratory & Blood Bank | LAB-084 | All Blood Bank Staff |
| Issue Date | Revision NO | Effective Date |
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| 23/07/1442 | CBAHI (LB 39, LB40) | 16 |

01. Policy:

Well trained phlebotomist must be alert in observing and recognizing signs of impending reactions, how to prevent and provide immediate proper treatment and how to do cardio-pulmonary resuscitation (CPR).

02. Definition :

Not applicable

03. Purpose :

Ensure proper and safe blood donation procedure

04. Procedure :

1. Materials needed for treating the reactions:

- 1.1. Cold compresses
- 1.2. Emesis basin or equivalent
- 1.3. Emergency supplies box or crush cart which contains anti-shock measures:
 - 1.3.1. Normal saline 500ml, Dextrose 5% 500ml and Ringer lactate
 - 1.3.2. Transfusion set
 - 1.3.3. Calcium gluconate

1.3.4. Corticosteroids ampule

1.4. Aromatic spirit of ammonia

1.5. Towels, tourniquet, alcohol swabs, cotton, gauze

1.6. Oxygen and mask

1.7. Donor medical history

1.8. Telephone to call the code blue in emergency cases

NOTE: In all cases of donor reaction, inform Blood Bank Physician to examine him as soon as possible. Staff should be trained for CPR and drug administration for dealing with emergency situation should be available.

In critical cases, the Emergency Department should be cooperative with Blood Bank Department and provide Emergency Team to deal with the case.

2. Patient preparation and suggestion for preventing possible donor reactions

2.1. Great the donor and make them familiar with the donor room.

2.2. Ask the donor to lie down on the bed or donor chair and allow them time to rest for not less than 5 minutes.

2.3. Lower the head of the donor before the start of donation.

2.4. During the donation, try to keep the donor's mind occupied with conversation or watching TV.

2.5. Do not allow donors to view the needle before insertion, or their own blood drawn since this alone may start a reaction.

2.6. The blood bank technician gives to the donor a leaflet related to the post donation instructions including also the blood bank phone number for the confidential self-unit exclusion.

3. The confidential self-unit exclusion

The donor can contact the blood bank staff at any time even if after a long period to inform that he feels that his blood is not suitable for the transfusion.

If the blood bank staff receives any notification or information from the donor himself or from a third party about the non-suitability of the blood for transfusion, he will document this information in especial logbook for self-unit exclusion then he will inform the blood bank physician then quarantine all the blood products for further actions.

the blood bank physician will review the case and decides to discard all the units of blood and blood products even if the serology results are negative.

If one or more units were already transfused at the moment of receipt of the information related to the self-unit exclusion, the doctor will contact the doctor in charge and do the look back for the case.

3.1.1.1.to avoid the danger of aspiration of vomitus.

3.1.1.2.Provide a suitable receptacle if the donor vomits and give him cleansing tissues.

3.1.1.3.You may give the donor a paper cup of water to rinse out his mouth.

Definitions of adverse events

A. Complications mainly with local symptoms

These complications are directly caused by the insertion of the needle.

Some of these are mainly characterized by occurrence of blood outside vessels, whereas others are mainly characterized by pain.

A 1. Complications mainly characterized by the occurrence of blood outside the vessels.

Hematoma (bruise)

Definition: A hematoma is an accumulation of blood in the tissues outside the vessels.

Mechanism: The symptoms are caused by blood flowing out of damaged vessels and accumulating in the soft tissues.

For apheresis procedures, hematomas may also be caused by infiltration of the soft tissues by red cells during the return phase of the procedure.

Large hematomas, particularly those in deeper layers of the forearm, put pressure on surrounding tissues and may contribute to other complications such as nerve irritation and injury and more rarely compartment syndrome.

Signs and symptoms: Bruising, discoloration, swelling and local pain.

Accumulation of blood in deeper tissues may result in more serious pain and pressure syndromes listed below.

Treatment

- Remove the tourniquet and the needle from the donor's arm.
- Place three or four gauze over the hematoma and apply firm pressure for 8-10 minutes with the donor's arm above the heart level.
- Should an arterial puncture be suspected, immediately withdraw needle and apply firm pressure for 10minutes. Check for radial pulse. If pulse is not palpable or weak, call a Blood Bank Physician.

Arterial puncture

Definition: Arterial puncture is a puncture of the brachial artery or of one of its branches by the needle used for bleeding the donor.

Mechanism: Because of the rapid blood flow, the risk of a large hematoma is increased and thereby risks of more serious pain and pressure syndromes listed below.

Signs and symptoms: A lighter red color than usual of the collected blood can be seen.

The needle and tubing may appear to pulsate; the blood bag fills very quickly.

There may be weak pain localized to the elbow region.

Delayed bleeding (re-bleeding) - optional category

Definition: Leakage of blood from the venipuncture site after the initial bleeding has stopped.

Mechanism: Re-bleeding may be related to pressure not being applied to the correct location or for an adequate duration, or premature removal of the bandage. After the donor has left the clinic, re-bleeding may be related to heavy lifting or strain to the donor's arm.

Donors on certain medications, such as autologous donors on anticoagulants, may be at higher risk to re-bleed.

Signs and symptoms: Spontaneous recommencement of bleeding from the venipuncture site, after pressure has been applied and the initial dressing has been removed, or leaking through the dressing.

A 2. Complications mainly characterized by pain

Nerve injury/irritation

Definition: Injury or irritation of a nerve

Mechanism: A nerve may be hit directly by the needle at insertion or withdrawal, or there may be pressure on a nerve due to a hematoma or inflammation of the soft tissues.

Include medically diagnosed cases, as well as cases reported on the basis of documented 'nerve' type symptoms. **Signs and symptoms:** Radiating, often 'electrical' sharp pain moving away from the venipuncture site, and/or paresthesia such as tingling, burning sensations in the hand, wrist or shoulder area but away from the venipuncture site.

Symptoms may arise immediately when the needle is inserted or withdrawn.

In cases associated with a hematoma, pain may not be apparent at the time and may start when the hematoma has reached a sufficient size, sometime after insertion of the needle.

Symptoms may be worse in certain positions or with certain arm motions. Rarely, weakness of the arm

may develop.

Optional split by duration of symptoms: Symptoms resolving within 12 months: Symptoms usually resolve within days, but rarely may persist for months or become permanent. Symptoms lasting more than 12 months.

Another Painful arm – optional category

Definition: Pain in the arm is the primary symptom, without the characteristics of nerve irritation outlined above, or the presence of a large hematoma or other defined complications that may be painful.

Mechanism: Pain may be related to tissue injury, possibly due to hematoma in the deeper tissues.

Signs and symptoms: Pain in the arm, without characteristics of nerve irritation.

May be described as an ache or heaviness in the arm, similar to that experienced after vaccination. Include all cases where arm pain is the main symptom, unless a diagnosis of nerve injury/irritation is suspected in the presence of nerve type symptoms recognized by trained staff.

A 3. Localised infection/inflammation Localized infection/inflammation

Definition: Inflammation along the course of a vein, which may progress to localized infection several days after phlebotomy. There may be clotting in the vein. Mechanism: Tissue damage and introduction of surface bacteria into the deeper tissues with venipuncture.

The superficial vein itself (thrombophlebitis) or the surrounding subcutaneous tissue (cellulitis) may be predominantly affected.

Signs and symptoms: Warmth, tenderness, local pain, redness and swelling at the site of phlebotomy.

The site and the vein may feel tender, firm, and warm to the touch.

Fever may be present.

Optional split into 2 categories:

Thrombophlebitis:

The redness, swelling, and tenderness extend along the course of the vein.

Cellulitis: The redness, swelling and tenderness affect the soft tissues, and are not localized to the course of the vein.

A 4. Other major blood vessel injury

These rare, serious conditions must always be medically diagnosed.

Deep venous thrombosis (DVT)

Definition:

Thrombosis of a deep vein in the donor's phlebotomy arm.

Mechanism: Superficial venous thrombosis may progress into the deeper veins of the donor's arm.

DVT may also rarely occur without previous signs and symptoms of superficial thrombosis.

An additional risk factor for thrombosis, in particular, the use of oral contraceptives, may be present in these donors.

Symptoms and signs: Swelling and pain in the upper arm.

May be accompanied by symptoms of superficial inflammation and thrombosis (see above).

Arteriovenous fistula

Definition: Acquired connection between the vein and artery due to venipuncture lacerations.

Mechanism: A channel forms between the lacerated vein and artery immediately postvenepuncture, or in the healing process. May be related to arterial puncture.

Signs and symptoms: Pulsating mass with a palpable thrill and associated bruit.

The affected area may be warm, and the distal part of the arm may be cool if significant shunting of blood is present.

The distal veins may be dilated and may pulsate.

Compartment syndrome

Definition: Increased intercompartment pressure leading to muscle and soft tissue necrosis.

Mechanism: Blood may accumulate in the frontal deep areas of the forearm, closing small blood vessels and resulting in muscle and nerve tissue necrosis. May be related to arterial puncture.

Signs and symptoms: Painful arm, particularly on movement; swelling, paresthesia and partial paralysis.

Brachial artery pseudoaneurysm

Definition: Collection of blood outside an artery, contained by adventitia or the surrounding tissues alone. Mechanism: After a traumatic arterial puncture, blood may leak out of the artery and accumulate in the surrounding space.

Signs and symptoms: Pulsating mass in the arm.

May be accompanied by pain and paresthesia.

May be preceded by a large hematoma following arterial puncture.

B. Complications mainly with generalized symptoms: vasovagal reactions

Definition: A vasovagal reaction (VVR) is a general feeling of discomfort and weakness with anxiety, dizziness and nausea, which may progress to loss of consciousness (faint). It is the most common acute complication related to blood donation.

Mechanisms: Both physiologic and psychological factors may be important. The reaction is generated by the autonomic nervous system and further stimulated by psychological factors and the volume of blood removed, relative to the donor's total blood volume.

Signs and symptoms: Usually several of the following: discomfort, weakness, anxiety, light-headedness/dizziness, nausea, chills, sweating, vomiting, pallor, hyperventilation, rapid or a slow pulse. Hypotension and loss of consciousness (LOC) may occur and can be accompanied by loss of bladder or bowel control or convulsive movements.

Reactions may occur before phlebotomy (rare), during phlebotomy or immediately after phlebotomy, when the donor stands up, in the refreshment area, or after the donor has left the collection site.

Most reactions occur within 12 hours of phlebotomy.

Reactions accompanied by LOC carry a risk of injury, particularly if they occur once the donor has left the collection site (delayed vasovagal reactions).

Vasovagal reactions are divided in two main subgroups:

Without loss of consciousness (LOC) - the donor does not faint

With loss of consciousness (LOC) - the donor faints for a period of time

Optional subdivision for donors

with LOC: LOC < 60 seconds - without other signs and symptoms

LOC ≥ 60 seconds - or with complications of convulsive movements, urinary or faecal incontinence

Optional subdivision:

With injury - Injury caused by falls or accidents in donors with a vasovagal reaction

Without injury

Optional subdivision:

Location of reaction:

On collection facility* - Symptoms occurred before donor has left the donation site

Outside collection facility - Symptoms occurred after donor has left the donation site *in area within

which staff can observe the donor and be responsible for the care of donors with complications

Faint : Treatment

Remove tourniquet and withdraw needle from the arm.

Apply cold compress to the donor's forehead or the back of the neck.

Place donor at his back on the floor with legs raised above the level of the head.

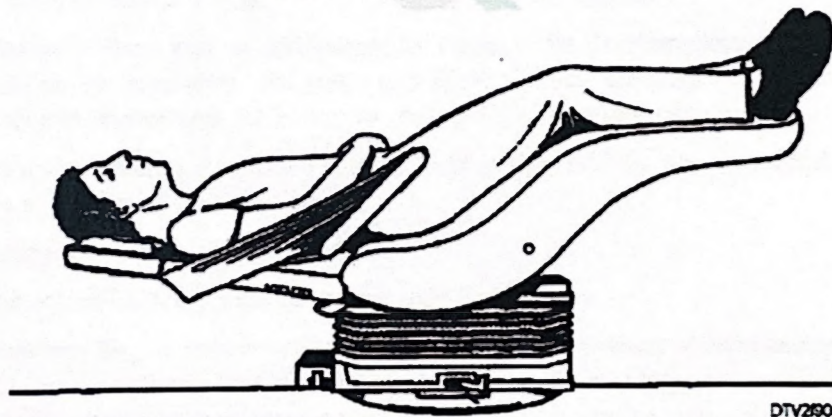
Loosen tight clothing.

Be sure donor has adequate airway.

Monitor blood pressure, pulse and respiration periodically until the donor recovers.

If no rapid recovery is achieved, call the Blood Bank Physician.

NB: The pulse rate often slows significantly. This can be useful in distinguishing between vasovagal attack and cardiogenic or hypovolemic shock, in which cases the pulse rate rises.



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Nausea and Vomiting Treatment

Instruct the donor to breath slowly and deeply if he is only nauseated.

Apply cold compresses to the patient's forehead and/or back of neck.

Turn donor's head to the side to avoid the danger of aspiration of vomitus.

Provide a suitable receptacle if the donor vomits and give him cleansing tissues.

You may give the donor a paper cup of water to rinse out his mouth.

C. Complications related to apheresis

Citrate reaction

Definition: Neuromuscular hyperactivity related to reduced ionized calcium levels.

Mechanism: Infusion of citrate anticoagulant during apheresis causes a fall in ionized calcium levels, leading to neuromuscular hyperactivity. If untreated, symptoms may progress to tetany and severe cardiac arrhythmias, including cardiac arrest. Operator error with mix up of saline and citrate bags may occur with some apheresis equipment, and lead to rapid citrate infusion.

Symptoms and signs: Numbness or tingling of lips, feelings of vibrations, numbness or tingling in the fingers, metallic taste, chills, shivering, light-headedness, feeling of tightness, muscle twitching, rapid or slow pulse, shortness of breath. Symptoms may progress to carpopedal spasms and vomiting, and in severe reactions, to generalized muscle contractions (tetany), shock, irregular pulse and cardiac arrest.

Hemolysis

Definition: Donor red cells may be damaged, releasing hemoglobin.

Mechanism: There may be malfunctioning valves, kinks or obstruction of the tubing, incorrect installation of equipment, or other equipment failures affecting the extracorporeal circuit. Incompatible replacement fluids, such as dextrose D5W, may be used in error.

Signs and symptoms: Pink or red plasma, blood in lines or filter may appear dark. The donor may notice pink or red urine after collection.

Air embolism

Definition: Air bubble introduced into the donor's circulation.

Mechanism: Air may enter into the lines due to incomplete priming of lines, as a result of a machine malfunction or defective collection kits or through incorrect manipulation by staff. Air in the donor's pulmonary circulation may occlude the pulmonary arteries in the lung and cause cardiopulmonary symptoms. Air may pass to the arterial circulation through an atrial septal defect, and reduce blood flow to the brain.

Signs and symptoms: Bubbling sound or feeling at the venipuncture site. Cough, dyspnea, apprehension, sweating, chest pain, confusion, tachycardia, hypotension, nausea and vomiting.

Optional category:

Infiltration

Definition: Intravenous solute (saline solution) enters the extravascular tissues during volume

replacement (generally only applicable to double red cell procedures).

Mechanism: The needle is no longer positioned in the intravascular space, so fluids enter the surrounding tissues.

Signs and symptoms: Swelling of the tissues at the venipuncture site.

Allergic reactions

Allergy (local)

Definition: Red or irritated skin at the venipuncture site.

Mechanism: Reaction caused by allergens or irritants in solutions used for disinfection of the arm (such as iodine or chlorhexidine) or in manufacture of the collection set. Irritation may also occur due to application of the adhesive bandage (bandage adhesive dermatitis). An allergic reaction to latex that may be in supplies such as gloves may also occur.

Signs and symptoms: Itching and redness at the venipuncture site, the bandage site, or the entire skin disinfection area. In a true allergic reaction, there may be a raised rash or hives in these areas that may expand to cover a larger area of the arm. The reaction may occur soon after donation or in the hours to days post-donation.

Generalized allergic reaction (anaphylactic reaction)

Definition: Anaphylactic type reactions usually starting soon after the procedure is begun and may progress rapidly to cardiac arrest.

Mechanism: Extremely rare reactions, attributed to donor sensitivity to ethylene oxide gas used to sterilize some collection kits.

Signs and symptoms: Apprehension, anxiousness, flushing, swelling of eyes, lips or tongue, cyanosis, cough, wheezing, dyspnea, chest tightness, cramps, nausea, vomiting, diarrhea, tachycardia, hypotension, and altered mentation.

Other serious complications related to blood donation

Major cardiovascular event (MCE)

Acute cardiac symptoms (other than myocardial infarction or cardiac arrest).

Myocardial infarction

Cardiac arrest

Transient Ischemic Attack

Cerebrovascular accident

Death

Reporting is encouraged of MCE or death from any cause up to 24 hours after donation, with an assessment of immutability.

Only cases with definite, probable or possible immutability should be included in international reporting.

Major cardiovascular events, including death, may occur in the hours after attending the collection centre for blood donation. This can occur without any relation to the donation (for deaths, this is described by the term actuarial deaths).

Serious Cardiac Difficulties

Treatment

If the donor is in serious cardiac difficulties or in cardiac arrest, announce code blue by calling 4444 & begin CPR immediately and confine him until code blue team arrive.

Convulsions

Treatment

Call for help immediately.

Prevent donor from injuring himself for you.

If possible, hold donor on bed. If not possible place the donor on the floor.

Be sure the donor has adequate airway.

Place a padded device to separate jaws after convulsions has ceased.

Notify Blood Bank Physician.

F. Other complications

Other systemic reactions or complications that do not fit into the above, such as chest pain that may have been investigated as angina, but was actually musculoskeletal, or transmission of infection to a donor through erroneous re-use of equipment.

Twitching or Muscular Spasms

Cause

Rapid breathing or hyperventilation may cause the anxious donor to lose excessive carbon dioxide. This may cause generalized sensation of suffocation or localized problems as faint muscular twitching of hands or face.

Treatment

Divert donor's attention by engaging in conversation to interrupt hyperventilation pattern.

Have the donor re-breathe into a paper bag.

Do not give oxygen.

Paresthesia or muscle cramping: **during platelets apheresis**

Symptoms may include abnormal sensations as tingling, prickling, burning, tightness, a feeling of band or girdle around the limb or trunk.

Most common sensations, tingling around the lips and finger tips is usually the result of Calcium deficiency because of Calcium binding by citrate.

Treatment

- Treat by slowing the reinfusion and centrifuge and do not begin another cycle until symptoms disappear
- Give four tetralin tablet to be chewed may be repeated every 15-20 minutes
- If symptoms still do not disappear, notify the blood bank physician.
- IV injection of Calcium gluconate may be indicated.

Grading of complication severity and immutability

Grading of severity - optional

Life-threatening complications and long-term disability are thankfully extremely rare after blood donation. Grading of severity for donor reactions does not easily fit into grading systems used for adverse reactions in patients. Use of this grading system is therefore optional. The criteria for classification of a reaction as serious (severe) as derived from these systems are:

Hospitalization: If it was attributable to the complication.

The criterion of hospital admission is applicable if a donor is kept in hospital overnight.

Cases where a donor is seen, examined, and in some cases given treatment (e.g. suturing, IV fluids, treatment of a fracture) but discharged home are not automatically classified as serious.

Intervention: To preclude permanent damage or impairment of a body function or to prevent death (life- threatening)

Symptoms: Causing significant disability or incapacity following a complication of blood donation and persisted for more than a year after the donation (Long term morbidity)

Death: If it follows a complication of blood donation and the death was possibly, probably or definitely related to the donation.

Types and definitions of reactions:

Certain complications of donation are by their nature mild or severe.

Local reactions - Most local reactions (hematoma, arm pain syndromes) would not be considered severe. Severe consequences are separate reaction types: deep venous thrombosis, arteriovenous fistula, and compartment syndrome. Nerve injury may rarely result in long term donor signs and symptoms. This may be captured by the duration of symptoms (optional split in nerve pain category).

Systemic reactions - Vasovagal reactions are characterized as those with or without LOC. There are two optional additional characteristics: LOC can be characterized as having additional symptoms (convulsions, loss of bowel or bladder control and/or duration of ≥ 60 seconds). Reactions can be categorized as resulting in injury or not.

Complications that are by their nature severe include generalized allergic (anaphylactic) reactions, and all major cardiovascular events.

Grading of immutability

The strength of relation between donation and complication is:

Definite or certain: When there is conclusive evidence beyond reasonable doubt for the relation.

Probable or likely: When the evidence is clearly in favor of a relation.

Possible: When the evidence is indeterminate for attributing the complication to the donation or an alternative cause.

Unlikely or doubtful: When the evidence is clearly in favor of attributing the complication to other causes. **Excluded:** When there is conclusive evidence beyond reasonable doubt that the complication can be attributed to causes other than the donation.

Immutability should only be reported for cardiovascular events leading to hospitalization or death post-donation, and only cases with immutability of possible, probable or definite should be captured.

Appendix 1: Summary table

Complications of donation

Optional categories or attributes are shown in *italics* and underlined

A. Local Symptoms

A1- Blood outside vessel

- Hematoma
- Arterial puncture
- Delayed bleeding

A2- Arm pain

- Nerve injury/irritation
 - duration < 12 months
 - duration > 12 months

- Another arm pains

A3- Localized infection/inflammation of vein or soft tissues

- Superficial thrombophlebitis
- Cellulitis
- A4 Other major blood vessel injury
- Deep Venous Thrombosis (DVT)
- Arteriovenous fistula
- Compartment syndrome
- Brachial artery pseudoaneurysm

B. Generalized symptoms

– Vasovagal Reactions

- Vasovagal Reaction, no loss of consciousness (LOC)
- Vasovagal Reaction, loss of consciousness < 60 seconds, no complications ≥ 60 seconds, and/or convulsions or incontinence
- With injury
- Without injury
- On collection site
- Off collection site

C. Related to apheresis

- Citrate reactions

- Hemolysis

- Air embolism

- Infiltration

D. Allergic reactions

- Local allergic reaction

- Generalized (anaphylactic) reaction

E. Other serious complications

- Acute cardiac symptoms (other than myocardial infarction or cardiac arrest).

- Myocardial infarction

- Cardiac arrest

- Transient Ischemic Attack (TIA)

- Cerebrovascular accident

- Death

F. Other For A-F, optional separate reporting of reactions classified as serious according to standard criteria (life-threatening or leading to hospitalization, incapacity, chronic morbidity or death).

04. Documentation, monitoring and reporting

The nature and treatment of all reactions are recorded on the donor records and a copy of the donor adverse reaction form **is kept in a special file.**

The blood transfusion reactions are monitored and monthly the blood bank supervisor or physician collects their statistics and analysis the causes then perform corrective actions (repeat training and competency for example)

05. Privacy and Confidentiality of Donors

Donor's selection criteria should be done in privacy and confidentiality should be maintained.

05. Responsibilities :

05.1. All Blood Bank Staff of Al-Qunfudah General Hospital.

06. Equipment & Forms

- 06.1. Crash cart with all supplies.
- 06.2. Crash cart check list
- 06.3. Donor adverse reaction form.
- 06.4. Self-unit exclusion log book



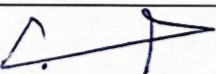
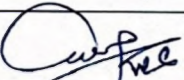

07. Attachment :

Appendix 1

08. Reference

- 08.1. Technical Manual of the American Association of Blood Banks.
- 08.2. AABB Standard for Surveillance of Complications Related to Blood Donation, 2014

Preparation, Reviewing & Approval Box

| | NAME | POSITION | SIGN & STAMP | DATE |
|----------------------|-----------------------|--------------------|---|-----------|
| Prepared By | Dr RAJA NACER SASSI | Head of Blood Bank |  | 16/8/1440 |
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| Document Reviewed By | Ms. SADIAH ALMAHMOUDI | TQM Director |  | 18/8/1440 |
| Reviewed By | Dr. AGEEL ALGANIMI | Medical Director |  | 18/8/1440 |
| Approved By | Dr. ABDULLAH ALJABRI | Hospital Director |  | 18/8/1440 |

